October 25, 2012

Celgene Reports Third Quarter 2012 Operating and Financial Results

— Total Revenue of $1.42 Billion and Net Product Sales of $1.39 Billion, Increased 14 Percent Y/Y

— Adjusted (Non-GAAP) Diluted Earnings per Share of $1.29, Increased 26 Percent Y/Y; GAAP Diluted Earnings per Share of $0.97 Increased 20 Percent Y/Y

— Raising 2012 Adjusted Earnings Guidance; Narrowing Revenue Guidance

— Over 150 Data Presentations Highlighting Our Products and Science at Major Medical Meetings Expected by Year-end

SUMMIT, N.J.--(BUSINESS WIRE)--Oct. 25, 2012-- Celgene Corporation (NASDAQ: CELG) reported total revenue of $1,419 million for the third quarter of 2012, a 14 percent increase from the same period in 2011. Adjusted (Non-GAAP) net income for the third quarter of 2012 increased 20 percent to $561 million compared to $469 million in the third quarter of 2011. For the same period, adjusted diluted earnings per share increased 26 percent to $1.29 from $1.02.

Based on U.S. GAAP (Generally Accepted Accounting Principles), Celgene reported third quarter 2012 net income of $424 million or $0.97 per diluted share. For the third quarter of 2011, net income was $373 million or $0.81 per diluted share.

“During the third quarter we generated excellent financial results and advanced major initiatives across our businesses that will serve as the foundation for future growth,” said Bob Hugin, Chairman and Chief Executive Officer of Celgene Corporation. “Positive results from late-stage studies for ABRAXANE, apremilast and pomalidomide create a solid path toward significant expansion of our portfolio and vital new options for patients in the future.”

Raising 2012 Earnings Outlook; Narrowing Revenue Guidance

- Adjusted diluted EPS is expected to increase approximately 29 percent year-over-year to a range of $4.85 to $4.90, up from a previous range of $4.80 to $4.85.
- Total revenue is expected to increase approximately 14 percent year-over-year to a range of $5,450 to $5,550 million. The previous range was $5,400 to $5,600 million.
- REVLIMID® net product sales are expected to increase approximately 18 percent year-over-year to a range of $3,750 to $3,800 million. The previous range was $3,750 to $3,850 million.

Third Quarter 2012 Financial Highlights

Unless otherwise stated, all comparisons are for the third quarter of 2012 compared to the third quarter of 2011. The adjusted operating expenses presented below exclude share-based employee compensation expense, upfront collaboration payments, non-core operations acquired from Abraxis and IPR&D impairments.

Net Product Sales Performance

Net product sales increased 14% to $1,388 million and reflect volume growth in the U.S., Europe and Japan. U.S. and international net product sales of $775 million and $613 million increased 11 percent and 19 percent, respectively.

- REVLIMID sales for the third quarter increased 18 percent to $970 million and were driven by overall market share gains, increased duration of therapy and geographic expansion. U.S. sales of $547 million and international sales of $423 million increased 17 percent and 20 percent, respectively.
- ABRAXANE® sales for the third quarter were $106 million, a 6 percent decrease. U.S. sales of $81 million declined 14 percent. In 2011, sales were positively impacted by generic paclitaxel shortages in the U.S. International sales of $25 million increased 29 percent due to volume growth and distributor purchasing patterns.

- VIDAZA® third quarter sales increased 15 percent to $220 million. U.S. sales increased 13 percent to $83 million. International sales increased 16 percent to $137 million, driven by gains in market share.
- THALOMID® sales were $75 million in the third quarter, representing a 10 percent decrease.

Research and Development (R&D)

Adjusted R&D expenses were $328 million for the third quarter compared to $307 million for the third quarter of 2011. The change is primarily due to increased clinical costs associated with advancing the mid- to late-stage pipeline and the absorption of the Avila Therapeutics acquisition which closed in March 2012. On a GAAP basis, R&D expenses were $442 million for the third quarter of 2012 and $357 million for the same period in 2011.

Selling, General and Administrative (SG&A)

Adjusted SG&A expenses were $323 million for the third quarter of 2012 compared to $276 million for the third quarter of 2011. The change was primarily due to increased ABRAXANE and REVLIMID marketing, in addition to pomalidomide pre-launch activities. On a GAAP basis, SG&A expenses were $355 million for the third quarter of 2012 compared to $303 million for the same period in 2011.

Cash, Cash Equivalents and Marketable Securities

Operating cash flow was $1,528 million for the first nine months of 2012, an increase of 14 percent compared to 2011. Under our authorized stock repurchase program, we purchased approximately 10.8 million shares during the third quarter of 2012 at a total cost of approximately $744 million. As of September 30, 2012, we had $2,417 million remaining under the existing stock repurchase program. During the third quarter of 2012, we issued an aggregate of $1,500 million in five- and ten-year bonds. We ended the third quarter with $3,833 million in cash and marketable securities.

Products & Pipeline:

We are conducting over 25 late-stage clinical trials. REVLIMID is in several phase III trials across a range of hematological malignancies that include newly diagnosed multiple myeloma and maintenance, lymphomas, chronic lymphocytic leukemia, and non deletion 5q myelodysplastic syndromes (MDS). Phase III trials with pomalidomide in relapsed refractory multiple myeloma and myelofibrosis, in addition to VIDAZA for acute myeloid leukemia, are also underway. In solid tumors, we are evaluating ABRAXANE in phase III trials for metastatic melanoma and pancreatic cancer. Our lead product candidate in Inflammation & Immunology, apremilast, is being evaluated in a broad phase III program for psoriatic arthritis, psoriasis, and ankylosing spondylitis.

Beyond our phase III programs is a growing early-to-mid-stage pipeline of novel therapies addressing significant unmet medical needs, including CC-292 (BTK inhibitor), CC-223 (dual TORK inhibitor), CC-115 (dual TORK/DNA PK inhibitor), CC-122 (pleiotropic pathway modulator), CC-486 (oral azacitidine), CC-220 (anti-inflammatory), PDA-001 (cellular therapies), in addition to partnered molecules ACE-11 (ActR fusion protein), ACE-536 (GDF trap), and EPZ-5676 (DOT1L inhibitor).

Key Updates:

Hematology

REVLIMID: We are advancing REVLIMID into new hematological malignancies. The pivotal phase II EMERGE trial in relapsed refractory mantle cell lymphoma achieved the endpoints outlined in the Special Protocol Assessment (SPA). Based upon these results, we will submit a supplemental new drug application (sNDA) to the Food and Drug Administration (FDA) by year-end. Presentation of the EMERGE data are expected at the American Society of Hematology (ASH) meeting in December.

During the first half of 2013, we expect a decision by the Committee for Medicinal Products for Human Use (CHMP) on REVLIMID for MDS deletion 5q and to complete enrollment in the phase III ORIGIN (CLL-008) trial in chronic lymphocytic leukemia.

Pomalidomide: The international phase III trial (MM-003) comparing pomalidomide with low-dose dexamethasone to high-dose dexamethasone in relapsed refractory multiple myeloma patients recently achieved the primary endpoint of progression-free survival, in addition to the key secondary endpoint of overall survival. The Phase I/II dose-ranging trial (MM-005) evaluating the combination of pomalidomide, dexamethasone and bortezomib continues with data expected at this year's ASH meeting. The regulatory reviews of pomalidomide for relapsed refractory multiple myeloma are progressing with an FDA decision expected in February 2013 and a CHMP decision expected during the second half of 2013.

Oncology

ABRAXANE: We are executing on the strategy to expand the label for ABRAXANE beyond the initial indication of metastatic breast cancer. In October, the FDA approved the second indication of ABRAXANE for the first-line treatment of locally advanced or metastatic non-small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.

The phase III trial evaluating ABRAXANE in metastatic melanoma achieved its primary endpoint of demonstrating a statistically significant improvement in progression-free survival compared to dacarbazine. Data will be presented at the Society for Melanoma Research meeting on November 11. Future regulatory and clinical strategies are being evaluated.

Results from the phase III trial in metastatic pancreatic cancer are expected in the fourth quarter of 2012. This trial randomized over 840 patients to receive gemcitabine with or without ABRAXANE. The primary endpoint is overall survival. If successful, this trial would support a sNDA submission in 2013.

Inflammation & Immunology

Apremilast: The PALACE program (PALACE-1, 2 and 3) demonstrated a robust and statistically significant clinical benefit in previously treated psoriatic arthritis (PsA) patients. Overall safety was consistent with previous experience in the phase II program with an improved tolerability profile. We anticipate presenting the PALACE-1 data at a medical meeting before year-end. Results from PALACE-4 in treatment-naïve psoriatic arthritis are expected during the first half of 2013.

The phase II trial (BCT-001) in patients with Behçet's disease achieved its primary endpoint of demonstrating a statistically significant improvement in the number of oral ulcers at day 85 between apremilast and placebo. Behçet's disease is a rare chronic inflammatory disorder with high unmet medical need that is characterized by recurrent oral and genital ulcers. We are currently reviewing future regulatory and clinical strategies in light of these data.

Results from the phase III ESTEEM program (ESTEEM 1 and 2) in moderate-to-severe psoriasis are expected by year-end and early 2013.

We plan to submit a NDA for PsA in the first quarter of 2013 followed by a sNDA for moderate-to-severe psoriasis in the second half of 2013 pending positive results from the ESTEEM program. A combined Marketing Authorization Application (MAA) submission to the European Medicines Agency (EMA) for PsA and moderate-to-severe psoriasis is planned for the second half of 2013.

Third Quarter 2012 Conference Call and Webcast Information

We are hosting a conference call to discuss the third quarter 2012 operating and financial performance on Thursday, October 25, 2012, at 9:00 a.m. ET. The conference call will be available by webcast at www.celgene.com. An audio replay of the call will be available from noon October 25, 2012, until midnight ET November 1, 2012. To access the replay, in the U.S. dial 800-585-8367; international dial 404-537-3406; and Participant Passcode 38153623. Our fourth quarter 2012 financial and operational results are expected to be reported in late January 2013.

About REVLIMID

In the U.S., REVLIMID (lenalidomide) in combination with dexamethasone is indicated for the treatment of multiple myeloma (MM) patients who have received at least one prior therapy. REVLIMID is indicated for patients with transfusion-dependent anemia due to Low- or Intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

About ABRAXANE

In the U.S., ABRAXANE for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated. In addition, ABRAXANE is indicated for the first-line treatment of locally advanced or metastatic non-small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.

About VIDAZA

In the U.S., VIDAZA is indicated for treatment of patients with the following French-American-British (FAB) myelodysplastic syndrome subtypes: refractory anemia (RA) or refractory anemia with ringed sideroblasts (RARS) (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T), and chronic myelomonocytic leukemia (CMMoL).

About Celgene

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of novel therapies for the treatment of cancer and inflammatory diseases through gene and protein regulation. For more information, please visit the company's Web site at www.celgene.com.

Forward-Looking Statements

This press release contains forward-looking statements, which are generally statements that are not historical facts. Forward-looking statements can be identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans," "will," "outlook" and similar expressions. Forward-looking statements are based on management's current plans, estimates, assumptions and projections, and speak only as of the date they are made. We undertake no obligation to update any forward-looking statement in light of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission.

In addition to financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted financial measures that we believe provide investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information. These adjusted measures are non-GAAP and should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. We typically exclude certain GAAP items that management does not believe affect our basic operations and that do not meet the GAAP definition of unusual or non-recurring items. Other companies may define these measures in different ways. See the attached Reconciliations of GAAP to adjusted Net Income for explanations of the amounts excluded and included to arrive at adjusted net income and adjusted earnings per share amounts for the three- and nine-month periods ended September 30, 2012 and 2011, and for the projected amounts for the year ending December 31, 2012.

Celgene Corporation and Subsidiaries
Condensed Consolidated Statements of Income
(Unaudited)
(In thousands, except per share data)

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2012	2011	2012	2011
Net product sales	$ 1,388,013	$ 1,219,118	$ 3,970,102	$ 3,457,055
Other revenue	31,238	30,619	89,201	101,118
Total revenue	1,419,251	1,249,737	4,059,303	3,558,173
Cost of goods sold (excluding amortization of acquired intangible assets)	74,622	94,645	218,994	348,356
Research and development	441,595	356,839	1,250,737	1,163,837
Selling, general and administrative	354,644	303,303	1,003,449	911,207
Amortization of acquired intangible assets	46,157	75,044	132,065	214,181
Acquisition related (gains) charges and restructuring, net	649	(11,209)	28,864	(117,430)
Total costs and expenses	917,667	818,622	2,634,109	2,520,151
Operating income	501,584	431,115	1,425,194	1,038,022
Other income (expense), net	(25,082)	(18,474)	(34,006)	(20,162)
Income before income taxes	476,502	412,641	1,391,188	1,017,860
Income tax provision	52,347	39,657	198,123	110,582
Net income	424,155	372,984	1,193,065	907,278

Non-controlling interest	-	-	-	694
Net income attributable to Celgene	$ 424,155	$ 372,984	$ 1,193,065	$ 907,972
Net income per share attributable to Celgene:				
Basic	$ 0.99	$ 0.83	$ 2.75	$ 1.97
Diluted	$ 0.97	$ 0.81	$ 2.69	$ 1.94
Weighted average shares:				
Basic	427,209	452,019	434,062	460,161
Diluted	436,272	459,530	443,432	467,052

	September 30, 2012	December 31, 2011
Balance sheet items:		
Cash, cash equivalents & marketable securities	$ 3,832,936	$ 2,648,154
Total assets	11,608,827	10,005,910
Short-term borrowings	324,895	526,684
Long-term debt	2,769,313	1,275,585
Total stockholders' equity	5,728,710	5,512,727

Celgene Corporation and Subsidiaries
Reconciliation of GAAP to Adjusted Net Income
(In thousands, except per share data)

		Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
		2012	2011	2012	2011
Net income attributable to Celgene - GAAP		$ 424,155	$ 372,984	$ 1,193,065	$ 907,972
Before tax adjustments:					
Total revenues:					
Sales of products exited or to be exited	(1)	-	(1,468)	-	(24,936)
Abraxis non-core other revenues	(2)	-	-	-	(1,714)
Cost of goods sold (excluding amortization of acquired intangible assets):					
Share-based compensation expense	(3)	3,314	2,627	9,173	7,054
Abraxis inventory step-up	(4)	-	6,945	-	90,278
Products exited or to be exited	(2)	(13)	4,008	(1,994)	19,288
Research and development:					
Share-based compensation expense	(3)	27,274	24,527	75,858	79,999
Abraxis non-core activities	(2)	-	-	-	8,728
IPR&D impairments	(5)	31,202	-	53,353	118,000
Upfront collaboration payments	(6)	55,000	25,000	130,000	65,982
Selling, general and administrative:					
Share-based compensation expense	(3)	32,119	27,198	86,010	75,905
Abraxis non-core activities	(2)	-	-	-	15,065

Amortization of acquired intangible assets	(7)	46,157	75,044	132,065	214,181
Acquisition related (gains) charges and restructuring, net:					
Change in fair value of contingent consideration	(8)	649	(11,377)	26,287	(122,547)
Acquisition and restructuring costs	(8)	-	168	2,577	5,117
Other income (expense), net					
EntreMed, Inc. equity method loss	(9)	-	53	-	542
Abraxis non-core activities	(2)	-	-	-	2,036
Gain on divestment of non-core activities	(10)	-	-	-	(2,931)
Non-controlling interest -Abraxis	(2)	-	-	-	(694)
Net income tax adjustments	(11)	(58,566)	(56,455)	(116,122)	(177,475)
Net income attributable to Celgene - Adjusted		$ 561,291	$ 469,254	$ 1,590,272	$ 1,279,850
Net income per share attributable to Celgene -Adjusted:					
Basic		$ 1.31	$ 1.04	$ 3.66	$ 2.78
Diluted		$ 1.29	$ 1.02	$ 3.59	$ 2.74

In addition to financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted financial measures that we believe provide investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information. These adjusted measures should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. We typically exclude certain GAAP items that management does not believe affect our basic operations and that do not meet the GAAP definition of unusual or non-recurring items. Other companies may define these measures in different ways. See the attached Reconciliations of GAAP to Adjusted Net Income for explanations of the amounts excluded and included to arrive aa Adjusted net income and adjusted earnings per share amounts for the three- and nine-month periods ended September 30, 2012 and 2011, and for the projected amounts for the year ending December 31, 2012.

Celgene Corporation and Subsidiaries
Reconciliation of GAAP to Adjusted Net Income

Explanation of adjustments:

(1) Exclude sales related to non-core former Pharmion Corp., or Pharmion, products to be exited and Abraxis BioScience Inc., or Abraxis, products that have been exited.

(2) Exclude the estimated impact of activities arising from the acquisition of Abraxis that are not related to core nab technology and were divested in 2011, including other miscellaneous revenues, cost of goods sold (excluding amortization of acquired intangible assets), operating expenses and other costs related to such activities. Exclude the net (benefit) cost of activities arising from the acquisition of Pharmion that are planned to be exited.

(3) Exclude share-based compensation expense totaling $62,707 for the three-month period ended September 30, 2012 and $54,352 for the three-month period ended September 30, 2011. Exclude share-based compensation expense totaling $171,041 for the nine-month period ended September 30, 2012 and $162,958 for the nine-month period ended September 30, 2011.

(4) Exclude acquisition-related inventory step-up adjustments to fair value which were expensed for Abraxis in 2011.

(5) Exclude in-process research and development, or IPR&D, impairment for the three-and nine-month periods ended September 30, 2012 related to obtaining approval for ISTODAX for the treatment of peripheral T-cell lymphoma, or PTCL, in the European Union. Exclude IPR&D impairment for the nine-month period ended September 30, 2011 related to a reduction in the probability of obtaining progression free survival labeling for the treatment of non-small cell lung cancer for ABRAXANE in the United States.

(6) Exclude upfront payments for research and development collaboration arrangements.

(7) Exclude amortization of intangible assets acquired from the acquisitions of Pharmion, Gloucester Pharmaceuticals, Inc., or Gloucester, Abraxis and Celgene Avilomics Research, Inc. (formerly known as Avila Therapeutics), or Avila.

(8) Exclude acquisition related charges and restructuring related to Gloucester, Abraxis and Avila.
(9) Exclude the Company's share of EntreMed, Inc. equity losses in 2011.
(10) Exclude the 2011 gain recognized on divestment of non-core activities obtained in the acquisition of Abraxis.
(11) Net income tax adjustments reflect the estimated tax effect of the above adjustments and the impact of certain other non-operating tax adjustments, including one-time effects of changes in tax law, acquisition related matters, an adjustment to the amount of unrecognized tax benefits and deferred taxes on unremitted foreign earnings.

Celgene Corporation and Subsidiaries
Reconciliation of Full-Year 2012 Projected GAAP to Adjusted Net Income
(In thousands, except per share data)

	Range	
	Low	High
Projected net income - GAAP	$1,622,000	$1,674,000
Before tax adjustments:		
Cost of goods sold (excluding amortization of acquired intangible assets):		
Share-based compensation expense	13,000	11,000
Research and development:		
Share-based compensation expense	104,000	93,000
IPR&D impairments	53,000	53,000
Upfront collaboration payments	165,000	160,000
Selling, general and administrative:		
Share-based compensation expense	115,000	104,000
Amortization of acquired intangible assets	200,000	194,000
Acquisition related (gains) charges and restructuring, net:		
Change in fair value of contingent consideration	29,000	29,000
Acquisition and restructuring costs	3,000	3,000
Net income tax adjustments	(160,000)	(155,000)
Projected net income - Adjusted	$2,144,000	$2,166,000
Projected net income per diluted common share - GAAP	$3.67	$3.79
Projected net income per diluted common share - Adjusted	$4.85	$4.90
Projected weighted average diluted shares	442,000	442,000

Source: Celgene Corporation

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